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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/786,492	Applicant(s) BAKER ET AL	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-6-2001</u> . | 6) <input type="checkbox"/> Other: ____ |

Handwritten initials

Specification

Applicant is requested to amend the first line of the specification to reiterate the claim to priority to PCT/EP99/06423.

Duplicate Claim Warning

Applicant is advised that should claim 13 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Likewise, the following sets of claims appear to be substantial duplicates:

- i) 14 and 18; and
- ii) 16 and 19.

Scope of Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-14, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for lowering tooth erosion potential using "complex" polysaccharides such as pectin, alginate or xanthan, does not reasonably provide enablement for using "viscosity modulating polymers" generally. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

While the relative skill of those in the art is high, this is outweighed by the highly unpredictable nature of the invention. The prior art recognizes that the ability of a given polymer to alter tooth erosion potential cannot be predicted *a priori*, and thus must be determined empirically on a case-by-case basis. See for example Van der Reijden et al ("Influence of Polymers for Use in Saliva Substitutes on De- and Remineralization of Enamel in vitro", *Caries Research*, vol. 31, pp. 216-223 (1997)); see the abstract and the discussion section of the last two pages of the article (note that polyacrylic acid actually damages tooth enamel).

2. The breadth of the claims

The rejected claims are extremely broad and inclusive of any and all possible "viscosity modulating polymer materials".

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no guidance for selecting any particular viscosity-modifying polymers, other than those specified at page 1, lines 20-26 and page 3, lines 1-25. All are what Applicant terms "complex" polysaccharides, except for one additional species (polyvinylpyrrolidone). The working examples also use those particular polymer types.

4. The quantity of experimentation necessary

Applicant fails to provide information allowing the skilled artisan to ascertain which polymers, other than "complex" polysaccharides such as gums, and polyvinylpyrrolidone, can be used to lower the tooth erosion potential of acidic oral compositions. In the instant case, only a limited number of polymers are exemplified in the specification working examples. It is noted that these examples are neither exhaustive, nor define the class of polymers required. The ability of polymers to reduce tooth erosion potential is unpredictable, requiring each species to be individually assessed. The instant claims are very broad and read on any "viscosity modulating polymer", encompassing an overwhelming number of possible species, necessitating an exhaustive and undue search for all the embodiments suitable to practice the claimed invention. Accordingly, applicant has failed to provide information sufficient to practice the claimed invention absent resorting to undue experimentation.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "complex" in claims 2 and 20 is a relative term which renders the claim indefinite. The term "complex" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. No guidance is provided as to how "simple" a given polysaccharide must be in order to be outside the scope of the instant claims.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Montezinos (USP 5,792,502).

The prior art discloses beverages which are vitamin fortified and thus "oral healthcare products" as required by instant claim 10 (see col. 10, lines 16-27). The beverages have pH's of 2.5 to 4.5, the acidity being adjusted and maintained in that range through the use of appropriate buffers (col. 9, lines 30-39). Since the same pH's are achieved using the same acidulants used by Applicant, one would

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reasonably expect the prior art beverages to inherently have the same titratable acidities as Applicant's beverages (0.01 to 4% w/w as recited by instant claim 12). The prior art beverages would also inherently contain minor amounts of soluble calcium salts derived from added water; see col. 8, lines 9-52 of the prior art, for example. (Any amount of calcium, no matter how minor, would be sufficient to anticipate instant claims 6, 7, 16 and 19, which only require the presence of calcium in an amount "up to" 0.8 mol.) The beverages are thickened by adding xanthan (one of Applicant's preferred "viscosity modulating polymers" of claim 3) to the preconcentrate, followed by adding water and an acidulant such as citric acid to attain the desired pH (see the passage bridging col. 10, line 49 to col. 11, line 8).

The preambles used throughout the instant method claims ("of reducing the tooth erosion potential" of acidic compositions and "of reducing tooth erosion caused by acid in orally administered compositions", specifically) are viewed as non-limiting since they do not recite essential steps "necessary to give life, meaning and vitality" to the claimed subject matter. See Pitney Bowes, 51 USPQ2d at 1165-66; Kropa v. Robie, 88 USPQ 478, 480-81 (CCPA 1951). The bodies of the claims following these preambles are self-contained descriptions of the claimed methods (simply adding a viscosity modulating polymer to an acidic oral composition; or simply "orally administering" the composition, which would be read upon by drinking same) and do not depend on the preamble for completeness. (And, in any case, where the prior art added and/or administered the same polymer to/in the same acidic oral composition as Applicant, one would reasonably expect the same reduction in tooth erosion potential to inherently occur as recited instantly).

2) Claims 13-23 are rejected under 35 USC 102(b) as being anticipated by Heckert (USP 4,722,847).

The prior art discloses fruit juice beverages to which have been added i) calcium, ii) an acidulant (col. 3, lines 45-57) and iii) a premix stabilizer, including polysaccharides such as pectin, aligins, starches and xanthan (col. 9, first paragraph). The premix stabilizer is added after calcium and the acidulant (col. 9, lines 15-17).

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As stated at col. 9, lines 32 and 33 of USP 5,792,502, a "pH range [of about 2.5 to about 4.5] is typical for noncarbonated beverages." Accordingly, one skilled in the art would reasonably expect the fruit juices of Heckert, which are typical noncarbonated beverages, to have pH's in the range of about 2.5 to about 4.5. (Note that USP 5,792,502 is cited herein only to illustrate that the inherent pH of fruit juices is well-known; the reference is not being used in combination with Heckert in the context of demonstrating obviousness.)

Although USP 4,722,847 is silent regarding pH control, it is noted that instant method claim 13 does not require same (claim 13 merely recites controlling pH "if necessary or desired", i.e. it is optional). Moreover, claims 14 and 18 do not mention pH control at all; they merely require a pH of less than or equal to 5. Furthermore, the specification does not define "orally administering" in any limiting fashion, such that the mere act of drinking the beverages of the prior art would be sufficient to meet that limitation.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-14 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/30601 in view of Heckert (USP 4,722,847).

The primary reference discloses tooth erosion inhibiting oral compositions (for use as beverages and for healthcare: see the first paragraph of the document) having pH's controlled to be in the range of 3.5 to 4.5, an acidulant in amount providing a titratable acidity of 0.1 to 4% w/w, and 0.3 to 0.75 moles calcium. See, for example, p. 4, lines 7-24. The primary reference differs from the instant claims insofar as it is silent regarding inclusion of a "viscosity modulating" polymer.

The secondary reference has been discussed at length in subsection "2)" of the "Anticipation" section supra, and differs from the instant claims insofar as it does not specify pH content or control. It teaches that the addition of a premix stabilizers such as pectin, algin and xanthan to fruit juice beverages is desirable to inhibit crystallization of added calcium. See col. 9, lines 1-17.

It would have been obvious to have added a premix stabilizer such as pectin, algin or xanthan, to the oral compositions of the primary reference, motivated by the desire to inhibit crystallization of the calcium added thereto, as taught by the secondary reference. Moreover, by stabilizing calcium – recognized by the primary reference to be a tooth erosion inhibiting agent – the act of adding a premix stabilizer will thus further reduce tooth erosion potential by optimizing the amount of calcium available in solution.

2) Claims 1-14 and 16-23 are rejected under 35 U.S.C. 103(a) as being obvious over Parker (USP 6,719,963) in view of Heckert (USP 4,722,847).

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The primary reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The primary reference is substantially cumulative of the primary reference applied in subsection "1) supra". Accordingly, it renders the instant claims obvious when taken in combination with Heckert, for substantially the same reasons provided in that subsection.

3) Claims 1-14 and 16-23 are rejected under 35 U.S.C. 103(a) as being obvious over Parker (USP 6,319,490) in view of Heckert (USP 4,722,847).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal

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disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The primary reference is substantially cumulative of the primary reference applied in subsection "1) supra. Accordingly, it renders the instant claims obvious when taken in combination with Heckert, for substantially the same reasons provided in that subsection.

Provisional Obviousness Rejection

Claims 1-14 and 16-23 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/733,992, which has a common inventor with the instant application, taken in view of Heckert (USP 4,722,847). Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The primary reference is substantially cumulative of the primary reference applied in subsection "1) of the "Obviousness" section supra. Accordingly, it renders the instant claims obvious when taken in combination with Heckert, for substantially the same reasons provided in that subsection.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The issues involved are largely repetitive, so the three conflicting applications will be discussed simultaneously in the interest of economy.

Rejections

1) Claims 1-14 and 16-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,719,963 in view of Heckert (USP 4,722,847).

2) Claims 1-14 and 16-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,319,490 in view of Heckert (USP 4,722,847).

3) Claims 1-14 and 16-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/733,992 in view of Heckert (USP 4,722,847).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Discussion

The conflicting claims of the two patents and one application are all drawn to acidic oral care compositions to which have been added calcium and an acidulant in order to reduce tooth erosion, and methods for preparing and using same. Accordingly, the conflicting claims differ substantially from the instant claims only insofar as they do not specifically incorporate a viscosity modulating polymer, e.g., pectin, algins or xanthan.

As previously discussed, the secondary reference teaches that the addition of a premix stabilizers such as pectin, algins and xanthan to fruit juice beverages is desirable to inhibit crystallization of added calcium. See col. 9, lines 1-17. Accordingly, it again would have been obvious to have added a premix stabilizer such as pectin, algins or xanthan, to the oral compositions of the primary reference, motivated by the desire to inhibit crystallization of the calcium added thereto, as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Fred Krass', written over the printed name and title.